510(k) Summary
(As Required by 21 C.F.R. §807.92)

DEC 1 8 2001

K004047

Submitted by:

Charlie Henry
President
In-X Corporation
10685 East 51st Street, Unit #2
Denver, CO 80239
Tel: 303.574.3115 x102
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Date of summary: December 27, 2000

Device name: In-X Home-Away System

Common name: Accessory to oxygen concentrator and liquid oxygen stroller

Classification names

Regulation Number	Classification Name
868.5440	Portable oxygen generator
868.5655	Portable liquid oxygen unit

Predicate Devices: The Puritan-Bennett Aeris 590 Oxygen Concentrator (K993088), and the Puritan-Bennett Companion Series Liquid Oxygen Reservoir (K861503 &K933930).

Intended Use: The In-X Corporation Home-Away System is intended as an accessory to an oxygen concentrator and liquid oxygen storage system for use as an aid or adjunct to delivering supplemental oxygen therapy in the home. It is intended to be used with both pediatric and adult patients. It is not intended to be a life sustaining or life supporting device. The device has no contraindications.

Technological Characteristics: Except for the liquefaction process, where gaseous oxygen is condensed by refrigeration to the liquid state (LOX), the Home Away System has the same technological characteristics as the legally marketed predicate devices. When it is connected to an oxygen concentrator, liquid oxygen is formed via a refrigeration unit similar to the compressor used in oxygen concentrators. The LOX is stored in a Dewar vessel similar to a LOX reservoir or stroller, where it can be transfilled to a portable LOX reservoir or stroller thereby providing the means for supplying the patient with supplemental oxygen.

Testing: Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the Home - Away System. Testing involved safety testing from the risk analysis. Other evaluations included laboratory studies for mechanical, electrical, environmental, and gas concentration properties. Acceptance criteria were based on either internal specifications, or those established in voluntary standards. All test results met acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

Mr. Charlie Henry
President
In-X Corporation
10685 East 51st Street, Unit #2
Denver, CO 80239

Re: K004047
The Home-Away System
Regulation Number: 868.5440/868.5665
Regulation Name: Portable Oxygen Generator/Portable Liquid Oxygen Unit
Regulatory Class: Class II (two)
Product Code: CAW/BYJ
Dated: October 24, 2001
Received: October 24, 2001

Dear Mr. Henry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

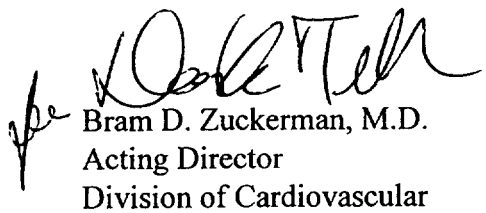
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K004047

Device Name The Home-Away System

Indications for Use The In-X Corporation Home-Away System is intended as an accessory to an oxygen concentrator and liquid oxygen storage system for use as an aid or adjunct to delivering supplemental oxygen therapy in the home. It is intended to be used with both pediatric and adult patients. It is not intended to be a life sustaining or life supporting device. The device has no contraindications.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K004047

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)